

## Patent

~~E~~Docket No. 455-023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

~~In the~~ application of

JEFFREY S. KIEL ET AL.

Serial No.: 10/806,260

: Group Art Unit: 1625

Filed: 03/22/2004

For: PHENOLIC ACID SALTS OF GABAPENTIN IN LIQUID  
AND/OR SEMI-SOLID DOSAGE FORMS AND METHODS OF USE

## INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

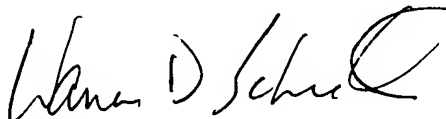
Applicant discloses to the Examiner under 37 CFR 1.56, and 37 CFR 1.97-1.98, as revised (1135 OG 13) and effective March 16, 1992, the information listed on the attached form PTO/SB/08A, Substitute for form 1449A/PTO. This information may be found to be material to this invention under the current applicable patent law and as interpreted by the US PTO Rules, as cited above. Review and consideration of the listed references/information during substantive examination of this application is respectfully requested.

Applicant specifically emphasizes that this statement, and/or the act of providing copies of these references, is not to be construed as an admission that all or any of the references are prior art to the specific invention disclosed and claimed.

Also, nothing in this statement is to be construed as a representation that this is the only material information to be found, or the best. It, however, is the only information known to the applicant at this time that is believed to meet the "materiality standard" of the law. If additional qualifying references or other information is discovered in the future, it will be submitted promptly to fulfill applicant's continuing duty of disclosure under 37 CFR 1.99.

Respectfully submitted,

**KING & SCHICKLI, PLLC**



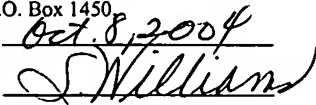
Warren D. Schickli  
Registration No. 31,057

247 North Broadway  
Lexington, Kentucky 40507  
(859) 252-0889

CERTIFICATE OF MAILING

I hereby certify that this correspondence  
is being deposited with the United States Postal  
Service as first class mail in an envelope addressed  
to: Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450, on Oct. 8, 2004

Date

Oct. 8, 2004 



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
 required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449A PTO

*(use as many sheets as necessary)*

Sheet

of

**Complete if Known**

<b>Application Number</b>	10/806,260
<b>Filing Date</b>	03/22/2004
<b>First Named Inventor</b>	JEFFREY S. KIEL
<b>Art Unit</b>	1625
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	455-023

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US- 6,306,904	10/23/2001	GORDZIEL	
	2	US- 6,117,452	09/12/2000	AHLGREN ET AL.	
	3	US- 5,759,579	06/02/1998	SINGH ET AL.	
	4	US- 5,614,178	03/25/1997	BLOOM ET AL.	
	5	US- 5,599,846	02/04/1997	CHOPDEKAR ET AL.	
	6	US- 5,164,398	11/17/1992	SIMS ET AL.	
	7	US- 5,025,019	06/18/1991	SUNSHINE ET AL.	
	8	US- 4,839,354	06/13/1989	SUNSHINE ET AL.	
	9	US- 4,767,402	08/30/1988	KOST ET AL.	
	10	US- 4,749,723	06/07/1988	SUNSHINE ET AL.	
	11	US- 4,749,722	06/07/1988	SUNSHINE ET AL.	
	12	US- 4,749,721	06/07/1988	SUNSHINE ET AL.	
	13	US- 4,749,711	06/07/1988	SUNSHINE ET AL.	
	14	US- 4,749,697	06/07/1988	SUNSHINE ET AL.	
	15	US- 4,619,934	10/28/1986	SUNSHINE ET AL.	
	16	US- 4,309,989	01/12/1982	FAHIM	
	17	US- 3,282,789	11/01/1966	MARTY ET AL.	
	18	US- 2,950,309	08/23/1960	CAVALLITO	
	19	US- 2,421,714	06/03/1947	RIEVESCHL	
	20	US- 2,397,799	04/02/1946	MARTIN ET AL.	

[illegible]

Examiner  
Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Business Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/806,260
		Filing Date	03/22/2004
		First Named Inventor	JEFFREY S. KIEL
		Art Unit	1625
		Examiner Name	
		Attorney Docket Number	455-023
Sheet		of	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	21	US- 6,740,312	05/25/2004	CHOPIN ET AL.	
	22	US- 6,703,044	03/09/2004	PINHASI ET AL.	
	23	US- 6,509,492	01/21/2003	VENKATARAMAN	
	24	US- 6,403,119	06/11/2002	OPPENHEIM ET AL.	
	25	US- 6,287,597	09/11/2001	GORDZIEL	
	26	US- 6,187,315	02/13/2001	FALCON	
	27	US- 6,063,770	05/16/2000	FALCON	
	28	US- 6,083,490	07/04/2000	ELLIS ET AL.	
	29	US- 6,037,358	03/14/2000	GORDZIEL	
	30	US- 5,663,415	09/02/1997	CHOPDEKAR ET AL.	
	31	US- 5,948,414	09/07/1999	WIERSMA	
	32	US- 5,560,933	10/01/1996	SOON-SHIONG ET AL.	
	33	US- 4,552,899	11/12/1985	SUNSHINE ET AL.	
	34	US- 6,462,094	10/08/2002	DANG ET AL.	
	35	US- 6,417,206	07/09/2002	LEFLEIN ET AL.	
	36	US- 5,132,451	07/21/1992	JENNINGS ET AL.	
	37	US- 5,095,148	03/10/1992	METTLER ET AL.	
	38	US- 5,068,413	11/26/1991	STEINER ET AL.	
	39	US- 4,024,175	05/17/1977	SATZINGER ET AL.	
		US-			

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/806,260	
		Filing Date	03/22/2004	
		First Named Inventor	JEFFREY S. KIEL	
		Group Art Unit	1625	
		Examiner Name		
Sheet		of	Attorney Docket Number	455-023

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	1	CYPRESS PHARMACEUTICAL, INC., "R-Tannic-S A/D," RX Only, Cypress Pharmaceutical, Inc., (Madison, MS), p. 1, 2 (March 1, 2001).	
	2	DSC LABORATORIES, "Phenylephrine Tannate/Pyrimilamine Tannate Suspension," RX Only, DSC Laboratories (Muskegon, MI), p. 1, 2 (Aug. 1, 2001).	
	3	RONALD GOLDBERG, M.D. and FRANKLIN SHUMAN, M.D., "Evaluation of a Prolonged Action Oral Antihistaminic Preparation as Treatment for Allergic Disorders," Clinical Report, Clinical Medicine (Washington), Vol. 72 (No. 9), pp. 1475-1479 (Sept. 1, 1965).	
	4	JOHN WEILER, M.D. ET AL., "Randomized, double-blind, parallel groups, placebo-controlled study of efficacy and safety of Rynatan in the treatment of allergic rhinitis using an acute model," Annals of Allergy, ACAI (Iowa City, IA), Vol. 64 (No. 1), p. 63-67 (Jan. 1, 1990).	
	5	BERGE et al. Pharmaceutical Salts. Journal of Pharmaceutical Sciences, Jan. 1977, vol. 66, No. 1, pp. 1-19.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.